Notice of Allowability	Application No.	Applicant(s)
	10/599,976	SCHELLER ET AL.
	Examiner	Art Unit
	MARCELA M. CORDERO GARCIA	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *2/10/2011*.

2. ☒ The allowed claim(s) is/are *1,14,16-18,20,24-36,40, 42-43,46-49,52,53 and 55*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Notice of Informal Patent Application
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)	6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20110509* .
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 3/16/2011	7. ☒ Examiner's Amendment/Comment
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. ☐ Examiner's Statement of Reasons for Allowance
	9. ☐ Other _____.
/MARCELA M CORDERO GARCIA/ Primary Examiner, Art Unit 1654	

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Leanne M. Rakers on 5/9/2011 and 5/11/2011.

The application has been amended as follows:

IN THE SPECIFICATION:

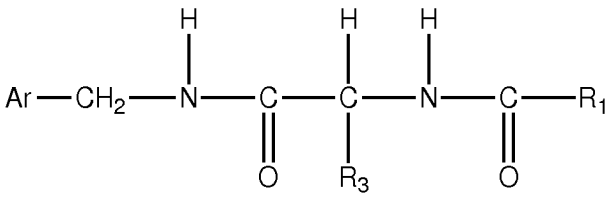
Please insert the following section title and paragraph at the top of page 4 of the specification as filed:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a picture demonstrating the location of drill holes in rat brain for the study discussed in the Example herein.

IN THE CLAIMS:

1. (previously presented) A method for treating a condition associated with cortical spreading depression (CSD) in a subject, comprising administering to the subject, in an amount effective to suppress CSD, a compound having the Formula (IIb)



Formula (IIb)

wherein

Ar is phenyl which is unsubstituted or substituted with at least one halo group;

R_3 is CH_2–Q, wherein Q is lower alkoxy containing 1–3 carbon atoms; and

R_1 is lower alkyl containing 1–3 carbon atoms,

or a pharmaceutically acceptable salt thereof, wherein the condition associated with CSD is a chronic headache selected from a group consisting of a muscle contraction headache, a toxic headache, a cluster headache, a traction headache, and an inflammatory headache.

2.-13. (cancelled)

14. (previously presented) The method of claim 1, wherein the compound is
(R)-2-acetamido-N-benzyl-3-methoxypropionamide;
O-methyl-N-acetyl-D-serine-m-fluorobenzylamide; or
O-methyl-N-acetyl-D-serine-p-fluorobenzylamide.

15. (cancelled).

16. (previously presented) The method of claim 1 wherein, in the compound of Formula (IIb), Ar is unsubstituted phenyl.

17. (withdrawn - previously presented) The method of claim 1 wherein, in the compound of Formula (IIb), halo is fluoro.

18. (previously presented) The method of claim 1 wherein, in the compound of Formula (IIb), R_3 is CH_2–Q, wherein Q is alkoxy containing 1–3 carbon atoms and Ar is unsubstituted phenyl.

19. (cancelled)

20. (previously presented) The method of claim 1, wherein the compound is substantially enantiopure.

21-23. (cancelled)

24. (previously presented) The method of claim 1, wherein the compound of

Formula (IIb) is (R)-2-acetamido-N-benzyl-3-methoxypropionamide.

25. (previously presented) The method of claim 24, wherein the compound is substantially enantiopure.
26. (previously presented) The method of claim 1, wherein the compound is administered at a dose of at least 100 mg/day.
27. (previously presented) The method of claim 1, wherein the compound is administered at a dose of at a maximum 1 g/day.
28. (previously presented) The method of claim 1, wherein the compound is administered at increasing daily doses until a predetermined daily dose is reached which is maintained during further treatment.
29. (previously presented) The method of claim 1, wherein the compound is administered in at most three doses per day.
30. (previously presented) The method of claim 1, wherein administration of the compound results in a plasma concentration of 7 to 8 µg/ml (trough) and 9 to 12 µg/ml (peak).
31. (previously presented) The method of claim 1, wherein the compound is administered for at least one week.
32. (previously presented) The method of claim 1, wherein the compound is administered orally.
33. (previously presented) The method of claim 1, further comprising administering to the subject a further active agent effective for prevention or treatment of a headache or a CSD-associated condition.
34. (previously presented) The method of claim 33, wherein the compound of Formula (IIb) and the further active agent are present in a single dose form.
35. (previously presented) The method of claim 1, wherein the subject is a mammal.
36. (previously presented) The method of claim 35, wherein the subject is human.
37. (cancelled)

38. (cancelled)
39. (cancelled)
40. (previously presented) The method of claim 33, wherein the compound of Formula (IIb) and the further active agent are present in separate dose forms.
41. (cancelled)
42. (previously presented) The method of claim 1, wherein the compound is administered at a dose of at a maximum 1 g/day.
43. (previously presented) The method of claim 1, wherein the compound is administered at a dose of at a maximum 400 mg/day.
44. (cancelled)
45. (cancelled)
46. (currently amended) A method of suppressing CSD to prevent or treat **a CSD-initiated** headache **in a subject in need thereof, the CSD-initiated headache** selected from the group consisting of a muscle contraction headache, a toxic headache, a cluster headache, a traction headache, and an inflammatory headache, the method comprising administering to the subject an oral effective amount of (R)-2-acetamido-N-benzyl-3-methoxypropionamide.
47. (previously presented) The method of claim 46, wherein the headache is cluster headache.
48. (previously presented) The method of any one of Claims 46 to 47, further comprising administering to the subject a triptan.
49. (previously presented) The method of claim 48, wherein the triptan is sumatriptan.
50. (cancelled)
51. (cancelled)
52. (currently amended) ~~**A method of suppressing CSD in a subject**~~, **The method of claim 46, ~~the method~~** comprising orally administering to the subject about 100 mg/day to about 400 mg/day (R)-2-acetamido-N-benzyl-

3-methoxypropionamide.

53. (previously presented) The method of claim 33, wherein the further active agent is effective for treatment of a CSD-associated condition selected from the group consisting of head injury, transient global amnesia, and intracranial hemorrhage.

54. (cancelled)

55. (previously presented - withdrawn) A method of treating in a subject a CSD-associated condition selected from the group consisting of a head injury, transient global amnesia, and intracranial hemorrhage, the method comprising administering to the subject an effective amount of (R)-2-acetamido-N-benzyl-3-methoxypropionamide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCELA M CORDERO GARCIA/
Primary Examiner, Art Unit 1654

MMCG 05/2011